

Remarks

Applicant has amended Claims 1, 20, and 76. Support for the claim amendments can be found throughout the specification, including, but not limited to, the following: Claim 1 on page 3, lines 21-26; Claim 20 on page 22, lines 1-17; and Claim 76 on page 3, lines 21-26. No new matter has been entered by the claim amendments and the Applicant respectfully request entry of the claim amendments.

I. Claim 20 rejected under 35 U.S.C. §112, second paragraph.

Applicant has amended Claim 20 to state a clear limitation. Applicant has amended Claim 20 to state lower scattering coefficient “ μ_s' according to the equation $\mu_{tot}' = \mu_a + \mu_s'$, where μ_a is the absorption coefficient and μ_{tot}' is the total attenuation coefficient”. As such, Claim 20 is definite in regards to a clear claim limitation, and the Applicant respectfully requests the Examiner to withdraw the rejection of Claim 20 under 35 U.S.C. §112, second paragraph.

II. Claims 1-4, 7-9, 11-31, 75 & 79-82 rejected under 35 U.S.C. §102(a) as being anticipated by Villard '2001

The Applicant has submitted a declaration under 37 C.F.R. §1.132 that the inventor, Joseph Villard conceived or invented the subject matter disclosed in the “Use of a Blood Substitute to Determine Instantaneous Murine Ventricular Thickening with Optical Coherence Tomography,” The University of Texas at Austin, submitted August, 2001 (Villard ‘2001 reference). A rejection based on 35 U.S.C. §102(a) can be overcome by filing a declaration under 37 C.F.R. §1.132 showing that the reference invention is not by another. *See* MPEP §706.02(b). The unequivocal declaration by Mr. Villard establishes that the Villard reference is describing Mr. Villard’s own work and that Mr. Villard conceived the subject matter disclosed in the Villard ‘2001 reference. As such, Mr. Villard’s declaration under 37 C.F.R. 1.132 is sufficient to remove the Villard ‘2001 Reference as a 35 U.S.C. §102(a) reference. The Applicant respectfully requests the Examiner to withdraw the rejection of Claims and the rejection of Claims 1-4, 7-9, 11-31, 75 & 79-82 under 35 U.S.C. §102(a) as being anticipated by the Villard ‘2001 Reference.

III. Claims 1-31, 57-63, 65-74, and 76 -78 rejected under 35 U.S.C. §102(b) as being anticipated by Rameshraja et al., Current aspects in pharmacology of modified hemoglobins, Advanced Drug Delivery Reviews, Volume 40, Issue 3, Blood Substitutes, 28 February 2000, Pages 185-198

The Examiner stated that Rameshraja teaches a method for performing treatment [wide variety conditions like trauma, elective surgery, oxygenation of tumors to make them more sensitive to radiation therapy, stroke etc.] of at least a first tissue in an animal, comprising providing into the blood associated with said at least a first tissue a biologically effective amount of a low scattering, oxygen-carrying blood substitute [Oxyglobin® having the inherent properties as disclosed in the Applicant's specification Page 24-25], and applying a treatment step [such as radiation therapy] to said at least a first tissue (Abstract, Page 185 Part I & Page 192 Part 2.6). First, Rameshraja does not teach or suggest "a method for performing an optical imaging or light-based treatment comprising providing into the blood associated with said at least a first tissue a biologically effective amount of a low-scattering, oxygen-carrying blood substitute, wherein the low-scattering, oxygen-carrying blood substitute is selected to substantially reduce optical scattering from the blood fraction whilst substantially maintaining tissue oxygenation, and applying an optical imaging or light-based treatment step to said at least a first tissue", to anticipate Claim 1. Rameshraja discusses hemoglobin-based blood substitutes and the pharmacologic properties of Hemoglobin inside and outside the red blood cell, as well as modification strategies to the hemoglobin molecule for its use in a blood substitute. Rameshraja does not mention the optical properties of hemoglobin blood substitutes or how they could be used as a strategy to reduce light scattering during diagnostic imaging or during light-based therapeutics. Consequently, Rameshraja is nonenabling to anticipate Claim 1 and insufficient to render Claim 1 unpatentable.

Secondly, the Examiner has not provided any rational or technical reasoning why Oxyglobin® could have inherent properties of "biologically effective amount of a low-scattering, oxygen-carrying blood substitute, wherein the low-scattering, oxygen-carrying blood substitute is selected to substantially reduce optical scattering from the blood fraction whilst substantially maintaining tissue oxygenation" as to anticipate Claim 1. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter.

1990). The Examiner cites to Applicant's specification on page 24-25; however, nothing on pages 24-25 of the present application indicates the low scattering properties of Oxyglobin®, nor indicates that Oxyglobin® inherently can be selected to substantially reduce optical scattering from the blood fraction whilst substantially maintaining tissue oxygenation. As such, Claim 1 is novel in light of Rameshraja, and the Applicant respectfully requests the Examiner to withdraw the rejection of Claim 1 in light of Rameshraja.

And regarding Claims 23-30, Rameshraja is silent as to the reducing the scattering coefficient of whole blood or the refractive index of the oxygen carrier being substantially equal to other molecular species in solution. Rameshraja is insufficient to anticipate Claims 23-30.

Regarding Claims 57-63 and 65-74, these claims are further believed allowable over Rameshraja for the same reasons set forth with respect to parent Claims 1 and since each dependent claim sets forth additional elements that are not disclosed in Rameshraja. Applicant asserts that the rejection of Claim 2, 3, 5, 7, 13-15 and 17 under 35 U.S.C. §102(a) has been overcome and should be withdrawn. Notice to that effect is requested.

Regarding Claims 76-78, Rameshraja does not teach or suggest a "low-scattering, oxygen-carrying blood substitute is selected to substantially reduce optical scattering from a blood fraction whilst substantially maintaining tissue oxygenation", as to anticipate Claim 76. Claims 77-78 depend from Claim 76, as such Claims 76-78 are not anticipated by Rameshraja. The Applicant respectfully requests the Examiner to withdraw the rejection of Claims 76-78.

Regarding the lack of unity regarding Group II for Claims 32-56, the Applicant submits that the technical feature of Claim 1 is novel and respectfully request rejoinder of Claims 32-56 upon the allowance of Claim 1.

Conclusion

According to the amendments and arguments presented above, the Applicant respectfully submits that the cited references fail to anticipate or render obvious the present invention and pending claims 1-31, 57-63, and 65-82 are in allowable form and allowance is respectfully requested.

No fees are believed due with this Response. However, the Director is authorized to deduct any deficiencies in fees from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner find that there are any outstanding matters which are susceptible of resolution by telephone interview; the Examiner is invited to telephone the undersigned to discuss the same.

Respectfully submitted



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